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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,834	02/13/2002	Johannes Booij	246152015300	5546

7590 04/06/2004  
Kate H Murashige  
Morrison & Foerster  
Suite 500  
3811 Valley Center Drive  
San Diego, CA 92130-2332

EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/937,834

Applicant(s)

BOOIJ ET AL.

Examiner

Mark L. Berch

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See memo.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See memo.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 10-14, 16-20, 25, 27-50.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Mark L. Berch  
Primary Examiner  
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#### DETAILED ACTION

The amendment filed 3/19/2004 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: The proposed amendment raises new issues that would require further consideration and/or search.

The claim 30-31, 38, 45 wording of "obtained without stirring...." limitation is unclear. Does this mean as compared to a solvent/antisolvent process that is just done without stirring (e.g. is done with shaking), or does it means compared with any other process done by any method other than that claim 10 method or what? In either case, it would appear that the public will be required to do an infinite amount of work to determine if the compounds does or does not fall outside this claim language. The public must try all possible methods (other than excluded ones) and do the comparison. This is because the comparison product is defined only in negative terms. This itself introduces a new issue.

The traverse of the rejection over 6417352 or 5288861 or 4454069 is unpersuasive. These references were not used against the process itself. Further, the claim does not forbid the K salt from being prepared in situ from the amine; the instant it is formed, the K salt is there in the solvents. As noted previously, it is not enough to show that the process is different. Applicants, for the compound claims, must show that the products are in fact different.

As for WO 98/21212, this applies to the process claims as well. The fact that the amine salt is present as a starting material does not distance the process from the claims. The exact instant the K salt is formed in that solution, it will meet the claim

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language requirement of Potassium clavulanate, and at that point, the solvent limitation is met as well.

Applicants refer to Table 1 in example 8. There is no way of knowing where this needle material came from.

With regard, to WO97/33564, much the same applies. Applicants argue that it deals with “agglomerates ... which are not clavulanates.” It is unclear how applicants can say this. Page 10 says, “Mixtures of agglomerates of a p-lactam antibiotic such as amoxicillin trihydrate with a second pharmaceutically active agent, e.g. potassium clavulanate....” Examples 7-11 all have Potassium clavulanate in the agglomerate.

The amendment, if entered, would have taken care of the first enablement rejection. The argument on the other (description) is unpersuasive. The specification says that applicants are preparing forms that have high water affinity (page 5, line 5). The present claims are extremely broad, covering the use of ANY solvent and ANY antisolvent, and thus would cover preparation of not only high water affinity forms, but also one that are not high water affinity forms, and hence beyond what the specification has.


Applicants are correct in that there is no claim 21.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch  
Primary Examiner  
Art Unit 1624

4/2/04